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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,431	06/05/2001	Karl Kolter	51497	5147

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/873,431	KOLTER ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,13,16-23 and 27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12,13,16-23 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of request for continued examination filed 07/11/05. Claims 1-9, 12, 13, 16-23, 25 and new claims 27-33 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 07/11/05 has been entered.

Petition and Terminal disclaimer:

The petition to withdraw the terminal disclaimer filed August 10, 2004 was granted and the new terminal disclaimer filed 03/07/05 has been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-9, 12, 13, 16-23, 25 and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description of what "finely dispersed" is and there is no description of how polyvinylpyrrolidone is "finely dispersed" in the polyvinyl acetate.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-7, 9, 12, 13, 16-23, 25 and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032).

Ortega discloses compressed tablet comprising theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68,. column 3, lines 57-63., and column 4, lines 3-18). The tablet composition is wet granulated from a mixture heated to 40 °C to 50 °C (example 1). Stearic acid is listed as an additive in the instant application (page 8, line 20) and the stearic acid of Ortega meets the limitation of additive recited in instant claim 25. How a composition is made carries no patentable weight in a composition claim. Ortega discloses a process of wet granulating a mixture of theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc (abstract; column 2, lines 56-68; column 3, lines 57-63; and column 4, lines 3-18) at a temperature of 40 °C to 50 °C (example 1). Regarding the molecular weight of the polyvinylpyrrolidone recited in instant claim 1, it is noted from the silence of Ortega on the molecular weight of the polyvinylpyrrolidone, that polyvinylpyrrolidone of any molecular weight can be used except declared by applicants to be contrary to Ortega's invention. Regarding the ratio of polyvinyl acetate to polyvinylpyrrolidone, it is within the purview of the person of ordinary skill or skill in the art to determine the relative amounts of the polyvinylpyrrolidone and polyvinyl acetate

necessary for a sustained or controlled release formulation. Ortega teaches a sustained release composition comprising theophylline, polyvinyl acetate and polyvinylpyrrolidone, cellulose acetate phthalate and optionally lubricant (abstract). Ortega specifically teaches that water-soluble polymers or gel forming polymers are used in the composition and the water-soluble polymers or gel forming polymers in Ortega are polyvinylpyrrolidone and cellulose derivatives such as hydroxypropylcellulose (column 3, lines 49-53). There is no demonstration in applicants' specification that shows that the particles size of 20-700 mm confers unusual results to the active agent. However, Ortega, while teaching wet granulation does not specifically disclose granulation by mixer granulation or fluidized bed granulation or extrusion granulation. But these forms of granulation are known processes of granulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to wet granulate the mixture of theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc according to Ortega. One having ordinary skill in the art would have been motivated to substitute one granulation process with another with the expectation of producing granules of the composition.

4. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032) in view of Noda et al. (US 5,389,380).

Ortega discloses the granulation of a composition that comprises theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc. Ortega does not teach a theophylline composition that contains lactose, cellulose powder, mannitol, calcium diphosphate or starch. Nonetheless, Noda discloses a theophylline composition comprising excipients such as lactose, sucrose, sorbitol and

mannitol and higher fatty acid or polyethylene glycol (column 4, lines 43-47 and column 5, lines 63-65); and Noda is relied upon for a teaching of theophylline composition that contains lactose or starch or mannitol excipient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising theophylline, polyvinylpyrrolidone, polyvinyl acetate, cellulose acetate phthalate and a mixture or stearic acid, magnesium stearate and talc. One having ordinary skill in the art would have been motivated to include excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol in the theophylline composition with the expectation of producing a sustained release formulation.

Response to Arguments

5. Applicants' arguments filed 03/07/05 and as with the filing of the RCE on 07/11/05 have been fully considered but they are not persuasive.

The previous rejection under 35 USC 102(b) is not made now because the introduction of "finely dispersed" changed the scope of the claims and also that Ortega does not specifically disclose finely dispersed. It is not persuasive that Ortega's dispersion of polyvinylpyrrolidone is not an evenly distributed because there is no demonstration that Ortega's dispersion is not evenly distributed --- no side by side experimentation data showing the different dispersions of the instant claims and the disclosed dispersion of Ortega. Applicants' granulation in the absence of solvent does not provide unexpected results over the process of Ortega and this response is also applicable to applicants' argument regarding claim 1 and 8 rejected over Ortega in view of Noda. The reliance on Noda for teaching theophylline composition comprising excipients such as lactose, sucrose, sorbitol and mannitool and higher fatty acid or polyethylene glycol is proper

since both references disclose theophylline. The argument about wet vs. dry granulation is addressed above.

Other Matters:

New claims 30 and 32 depend on cancelled claims and correction is respectfully requested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600